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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,351	10/29/2003	Kenneth F. Buechler	071949-1328	7522
30542	7590	04/07/2006	EXAMINER	
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,351	<b>Applicant(s)</b> BUECHLER, KENNETH F.	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 27 January 2006.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-7 is/are pending in the application.  
    4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-7 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1743

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 6-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12; 1-50; 1-15; 1-25; 1-12 of U.S. Patent No. 5,885,527; 6,019,944; 5,458,852; 6,271,040; 6,905,882 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an assay device for detecting one or more ligands.

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-14,25-37; 1-44 of U.S. Patent No. 6,767,510 and 6,156,270 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an assay device having a roughened surface for detecting one or more ligands.

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-24 of

Art Unit: 1743

copending Application No. 11/022, 297 and 10/792,258 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an assay device for detecting one or more ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite what is intended by a "nonporous surface". The original specification does not appear to describe what materials would create the claimed "nonporous surface". Additionally, the particle size range is confusing if diameter is intended. The original specification does not provide any discussion if diameter is intended.

Claim 6 is confusing what structure is contemplated by the claimed second surface and how it interacts with the nonporous surface.

Claim 7 is vague and indefinite the meets and bounds of the claim. No structure is claimed that further limits the subject matter of any one of the previous claims 1-5. Apparently, this claim is directed to claiming the absence of a structure (e.g. absence of a capillary space) and is not readily understood.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Findlay et al. (USP 5,514,550), Wu (USP 5,387,510).

In light of the above 35 USC 112 issues, the claims are best understood as a nonporous surface with immobilized particles that have binding receptors.

The effective filing date of this application has been determined as 7/11/00 because the parent USPs 6,156,270, 6,143,576 and 6,271,040 do not contain the presently claimed "nonporous" surface.

Findlay et al. teach an assay device having a nonporous surface (see col. 14 lines 9+) with particles immobilized to the surface. Column 6 lines 31-41 teach the particles are in the range of 0.1-10 microns and preferably between 0.1 and 5 microns (also see claim 3). The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. Column 6 lines 36-41 teach the claimed materials of the particles. Example 2 in column 13 expressly teaches the particles are made of polystyrene.

Wu teaches a nucleic acid amplification kit. Column 10 lines 47-64 teach the surface can be nonporous. Column 9 lines 3-9 teach the particles immobilized on the surface could be from 0.01-10 microns. Column 9 lines 38-50 teach the particles can

Art Unit: 1743

be made of polystyrene. The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles.

***Response to Arguments***

Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' remarks stating USP 5,922,615 and 6,297,060 were convincing in that these patents do not teach a nonporous substrate. The Obviousness Type Double patenting rejections over USP 5,922,615 and 6,297,060 have been vacated.

Applicants' comments concerning the provisional Obviousness Type Double patenting rejection over 09/982,629 were correct in noting the application is now USP 6,905,882 and this provisional rejection should be dropped in favor of the Obviousness Type Double patenting rejection over the patent, which is of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

A handwritten signature in black ink, appearing to be 'Lyle A. Alexander', written in a cursive style.